

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION |) | MDL NO. 1203 |
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| THIS DOCUMENT RELATES TO: |) | |
| SHEILA BROWN, et al. |) | |
| v. |) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION |) | 2:16 MD 1203 |

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8254

Bartle, C.J.

August 19, 2009

Cheryl East De Amici ("Ms. De Amici" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Dr. Stephen Raskin, M.D. Based on an echocardiogram dated October 30, 2002, Dr. Raskin attested in Part II of Ms. De Amici's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of

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contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.³

In the report of claimant's echocardiogram, the sonographer, M.J. Quinn, observed that claimant had a moderate mitral regurgitation ratio of 28%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. In addition, the sonographer found that claimant had an enlarged left atrium measuring 4.14 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. at § IV.B.2.c.(2)(b). The sonographer also noted that claimant's ejection fraction was 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is among the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

In November 2005, the Trust forwarded the claim for review by Karen K. Hamilton, M.D., one of its auditing cardiologists. In audit, Dr. Hamilton determined that claimant's level of mitral regurgitation was mild and that there was no reasonable medical basis for Dr. Raskin's finding of moderate mitral regurgitation. In support of this conclusion, Dr. Hamilton explained that "[m]ost of the MR jets seen are less than 20% of LA area Also the color gain on this study is very high, which may result in the overestimation of the size of the color jets." Dr. Hamilton also found claimant's ejection fraction to be greater than 60%. Finally, Dr. Hamilton concurred with Dr. Raskin's finding that claimant had an abnormal left atrial dimension.

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. De Amici's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁴ In contest, claimant submitted a declaration from Dr. Raskin, who asserted that his original findings were correct. Specifically, Dr. Raskin wrote:

4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. De Amici's claim.

While some inter-observer variability in planimetry of the mitral color jet is likely, in this case, such variability does not substantively change the basis for the presence of moderate mitral regurgitation based on the AHP Trust definition The determination of moderate MR using color flow, as originally described by Helmcke et al. and referenced by Singh et al. in the Green Form, requires that only one orthogonal view demonstrate a regurgitant jet area/left atrial area ratio of at least 20 percent. Even nearly a 25% overestimate of the regurgitant jet area in this case would not alter the conclusion, based on the AHP Trust definition, that moderate MR is present.

Dr. Raskin also stated that "[e]xcessive color gain or the so-called 'dial-a-jet phenomenon' is not present in the De Amici case since there is no observable 'bleeding' of color onto the gray scale of the surrounding tissue, nor is there any background color speckling evident in the tissues." Moreover, Dr. Raskin concluded that "[e]xcessive gain, defined by increased color [pixelation] in non-moving anatomic regions, is not supported by my review of the October 30, 2002 De Amici study."

The Trust then issued a final post-audit determination, again denying Ms. De Amici's claim. In its letter, the Trust asserted that Dr. Raskin's letter does not establish a reasonable medical basis for a finding of moderate mitral regurgitation because the attesting physician "fails to refute Dr. Hamilton finding's [sic] of 'non-aliased blue flow'" Moreover, the Trust contested claimant's interpretation of PTO No. 2640, in which, according to the Trust, the court did not suggest that a finding of moderate mitral regurgitation could be based on a

single frame, but ruled instead that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved." See PTO No. 2640 (Nov. 14, 2002) at p. 9. The Trust averred that a jet must be "sustained" in order to be true mitral regurgitation.

Claimant disputed this final determination and requested that her claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. De Amici's claim should be paid. On May 11, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6264 (May 11, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁵ to review claims after the Trust and

5. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are

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claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. De Amici reasserts the arguments she made in contest, and argues further that the Trust disregarded Dr. Raskin's declaration and findings. Claimant

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conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

notes that "Dr. Raskin respectfully disagrees with Dr. Hamilton regarding the degree of mitral regurgitation present in [claimant's] October 30, 2002 echocardiogram and firmly reasserts his initial findings of moderate mitral regurgitation." Claimant also argues that Dr. Raskin never asserted that actual measurements, rather than mere "eyeballing" of jets, were necessary.

In response, the Trust reiterates the arguments addressed in the final post-audit determination. The Trust also contends that, in reaching his determination, "Dr. Raskin relied on standards that are contrary to generally accepted medical principles as well as the Settlement Agreement as interpreted by the Court and, hence, Dr. Raskin's finding lacks a reasonable medical basis."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Abramson determined that:

In reviewing the transthoracic echocardiogram from 10/30/02, my visual estimate is that there is moderate mitral regurgitation, which is present in all of the apical views. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in three cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $3.7\text{cm}^2/13.9\text{cm}^2$, $4.6\text{cm}^2/15.3\text{cm}^2$ and $4.9\text{cm}^2/15.6\text{cm}^2$. These ratios are 27%, 30%, and 31%, all of which are between 20% and 40%, which is consistent with moderate mitral regurgitation. The Doppler settings on the

tape including the color gain and the Nyquist limits are appropriate. I agree with the measurements on the tape. I also think that the still frames in Exhibits B and C of the claimant's Response are true representations of this mitral regurgitant jet.

After reviewing the entire show cause record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding of moderate mitral regurgitation.⁶ Specifically, Dr. Abramson concluded that "[t]here is a reasonable medical basis for the Attesting Physician's claim that Cheryl East De Amici has moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Abramson found that claimant's RJA/LAA ratios were 27%, 30% and 31%, which is consistent with moderate mitral regurgitation. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. Accordingly, we need not address claimant's remaining arguments.

6. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34. Claimant submitted a response, stating that she agreed with Dr. Abramson's findings.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. De Amici for Matrix benefits.